Chapter 4
The Healthcare Regulatory Ecosystem

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Abstract Healthcare is a complex adaptive system, with considerable fragmentation between healthcare institutions and medical specialisations. The regulation of safety in healthcare involves both formal (legislation, accreditation procedures, policies, procedures) and informal (professional standards, ethical principles, accepted modes of care) components. These instruments are complemented by self-regulation by clinicians and by patients who invest in understanding their ailments and selecting desired treatment modes. In recent years, the Safety-II approach is increasingly recognised as an important regulatory paradigm.

Keywords Patient safety · Regulation · Self-regulation · Regulatory paradigms · Safety-II

4.1 Introduction

At least as much as other safety environments and sectors discussed in this volume, healthcare is a complex adaptive system (CAS). This means that it exhibits certain features that challenge regulators and regulatees. CASs involve multiple stakeholders (individuals, organisations, institutions) interacting over time to create policy, treatment, and care. A CAS follows rules, some of which are self-directed, others which are formally enacted, and yet others which are externally regulated. The capacity of stakeholders to self-organise, exhibit emergent behaviour, learn, and adapt flexibly over time are inherent features of the healthcare CAS. Those who study such complex systems have observed common characteristics in examples from cities to markets to social networks to organisations (Axelrod and Cohen 2000; Waldrop 1992). Key features of complex adaptive healthcare systems are presented in the accompanying box (Box 4.1) (Braithwaite et al. 2018a, 2017).

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Box 4.1. Key features of healthcare complexity

- A multiplicity of dynamic clinical, policy, and managerial networks
- Agents interact over time to create outputs (e.g., policy, care)
- Path dependence dictates that historical antecedents shape current behaviours
- The ensemble of relationships evokes behaviours that are not predictable
- Behaviours are typically emergent
- Clinical behaviours exhibit degrees of freedom from standard operating procedures (SOPs)
- Patients, too, have considerable agency
- Systems adjustments and modifications are typically incremental, but when circumstances dictate or pressures build, a phase transition can occur
- Nonlinearity means that change is not uniform and can be chaotic and counterintuitive.

In the healthcare CAS, it is not only the *characteristics* of complex care which stimulate the regulatory regime. It is also the tests of regulatory efficacy: the *public interest test* (how can we protect society?), the *economic benefits test* (how can we promote cost-beneficial care?), and the *patient safety test* (how can we keep patients safe?). In attempting to satisfy these tests, regulators must take account of the sheer complexity of the healthcare ecosystem. Essentially, they are seeking to ensure the integrity of the system and the quality of care provided across the plurality of healthcare markets and services.

With that introduction in mind, healthcare conceptualised as a CAS can now be defined. The healthcare CAS has multiple agents (e.g., patients, clinicians, and other professional and support personnel, managers and leaders, policymakers, politicians and agencies including those responsible for financing, standards-setting, assuring quality of care, assessing professional staff, and providing care). Healthcare is structured into sectors (acute care, primary care, aged care, rehabilitation, tertiary, and quaternary care). The numbers of patient types and conditions for which patients require treatment are very large, as are the range of drugs, procedures, treatments, and care protocols. Each of the sectors and their delivery organisations require differing levels and types of regulatory frameworks (Braithwaite et al. 2018b).

This means there is a vast range of markets and market considerations facing regulators. In the main, regulation is conducted through various types of enactment by authorised bodies and agencies, e.g., legislation and legislative instruments, policies, procedures, standards, and guidelines, and then inspecting, credentialing, authorising, and certifying against those enactments. Informal regulation emanates from professionally recognised standards, ethical principles, and accepted modes of practicing and caring for patients. There is also a great deal of choice exercised by clinicians on the front-lines of care and by patients on the ground.

4.2 Literature Review

A brief examination of some key healthcare regulation studies can help further with background understanding, illustrating how widespread regulation has become. There are examples ranging from society-level regulatory approaches, e.g., taxes on sugary drinks (Fenton 2019; Wilkinson 2019); through to medical device regulation (Vasiljeva et al. 2020; Kramer et al. 2012); regulation of clinical practice (Yang et al. 2021; Jovic et al. 2015); social regulation and bottom-up aspects of professional values (Bringedal et al. 2018); and a range of others including e-cigarette regulation (Rose et al. 2015); patient safety regulation (e.g., Oikonomou et al. 2019); clinical trial regulation (Knaapen et al. 2020); regulation of abortions in the US (Dodge et al. 2012); and regulation of home-based care (Daumit et al. 2019) (Table 4.1).

The table draws attention to the range of regulatory activities that have been researched. The landscape of regulation is thus fragmented. In the English NHS, for example, a study by Oikonomou and colleagues (Oikonomou et al. 2019) found that there were 126 organisations exerting some level of regulatory influence over providers of various kinds. Thus, healthcare complexity is being met by a propensity of complex regulatory activities. We turn to a more detailed examination of these activities.

Table 4.1 Selected studies of regulation in healthcare

Description	Reference
Medical device regulation in the EU	Vasiljeva et al. (2020)
E-cigarette regulation: comparative national regulation approaches	Rose et al. (2015)
Obesity regulation: taxes on sugary drinks	Fenton (2019)
Medical device regulation in the EU and US	Kramer et al. (2012)
Nurse practitioner regulation in the US	Yang et al. (2021)
Patient safety regulation in the English National Health Service (NHS)	Oikonomou et al. (2019)
Obesity regulation: sugar tax and limiting fast food outlet density	Wilkinson (2019)
Regulation of nurses in France	Jovic et al. (2015)
Clinical trial regulation in the EU	Knaapen et al. (2020)
US State-level regulation of abortions	Dodge et al. (2012)
Regulation of behavioural health home (BHH) models for integrating physical and mental healthcare in the US	Daumit et al. (2019)
Social regulation and professional values in Norwegian medical doctors	Bringedal et al. (2018)

4.3 Regulation of and in Healthcare

There are extremely important public interest and health considerations in providing clinical care. Healthcare is high-tech and high-touch simultaneously and, although the benefits of providing good quality care to patients are considerable, things can go wrong. Harm befalling patients is estimated, depending on how it is measured, to run at about 1:10 admissions and encounters. Most of these incidents are minor in nature, but serious adverse events can and do occur in every health system. A proportion of all incidents, perhaps a third, is thought to be preventable.

Harm is in the mind of regulators, and healthcare quality and waste are also important. Some 60% of care is in line with level 1 evidence or consensus-based guidelines, up to 30% is waste, and 10% is related to some form of harm (Braithwaite et al. 2020) (see Fig. 4.1). This 60-30-10 idea is increasingly the focus of policymakers, clinical colleges and healthcare organisations as well as regulatory authorities and agencies.

This 60-30-10 paradigm is a systems view of the challenges facing healthcare: by raising the 60%, and reducing the 30 and 10%, the care provided by the system would be improved (Braithwaite et al. 2020). Amalberti et al., presaging this idea (e.g., Amalberti 1996; Amalberti et al. 2005), have also written on health systems. The systems approach he and Vincent have championed has been influential (Vincent and

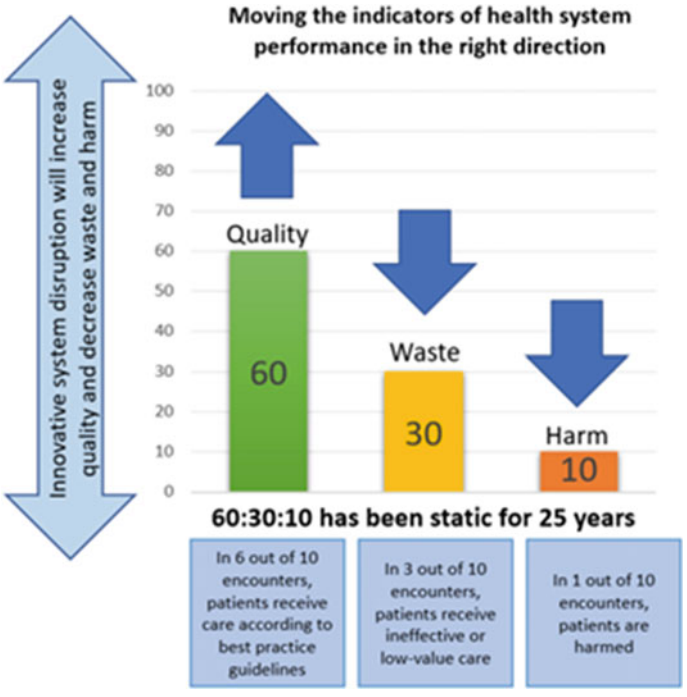

Fig. 4.1 60-30-10 paradigm

Amalberti 2016). With colleagues, Amalberti has considered ultrasafe care (Amalberti et al. 2005), barriers to safety (Amalberti et al. 2005), and real-world strategies towards safer, higher-quality care (Vincent and Amalberti 2016). He advocates improving the system and its processes, which is especially challenging in an era of technological, sociological, political, and economic change.

These considerations bring us to the changing role of regulators in ensuring that high-quality, safe care is provided. Regulatory effort has traditionally been aimed at preventing, reducing, or eliminating harm at the societal level, or for specific patients and patient groups. This has been labelled Safety-I (Hollnagel et al. 2013). It involves regulatory prescribing or legislating to ensure practitioners act safely and provide acceptable standards of care. It assumes that things go wrong and that efforts should be made to reduce incidents and adverse events, such that the system gets as close as possible to zero harm.

Some experts think that in a system this complex, zero harm is not merely unattainable, but a misguided goal. Over the last eight years, approaches towards promoting a Safety-II paradigm, looking at how things go well, have been articulated (e.g., Wears et al. 2015). These approaches ask a powerful question—how does care go right so often, given the complexities of healthcare and the propensity for things to go wrong? The perspective here is to consider the extent to which the system exhibits resilient performance: can it sustain its operations while facing both expected and unexpected conditions, and doing so by making continual adjustments in response to changes, disturbances, opportunities, and threats. Such resilient performance for Hollnagel is feasible if four potentials are pursued: the potential to respond; to monitor; to learn; and to anticipate. These four potentials are collectively known as the resilience assessment grid (Hollnagel 2017).

Regulation and regulatory authorities have not completely caught up with this shift in mindset and the focus on how systems succeed and enhance the ability to succeed more often under complex variable conditions and circumstances. Nevertheless, some countries, e.g., the Netherlands, Australia, and the Scandinavian countries, are increasingly reflecting a Safety-II view in their regulatory responses.

4.4 The Australian Health System as an Exemplar

By way of providing a country-level example of the complexities of healthcare regulation, the next table (Table 4.2) summarises some of the main regulatory mechanisms of Australian healthcare (Australian Government Department of Health 2021). It is more extensive than this table depicts, as the direct and indirect effects of each regulatory initiative are felt across the macro-, meso- and micro-levels of the system. But these are some of the more prominent forms of regulatory structures and foci. These functions and roles are mirrored in other healthcare systems.

By way of responding to these formal regulatory agencies and bodies, for the most part healthcare organisations and private providers try to adhere to their requirements. This is because the majority of regulation has the force of law or comes with incentives

Table 4.2 Selected aspects of the regulatory environment and structure of Australian healthcare as an exemplar

	Governance mechanisms	AHPRA	IHPA	ACSQHC	TGA	PBAC
Role, purpose	Multiple (federal, state, and local)	Regulation of health practitioners and clinicians	Regulation of hospital pricing using diagnostic-related groups	Regulation of standards of care	Regulation of all forms of 'therapeutic goods'	Regulation of different kinds of new medicines
Federal/central/macro	✓	✓	✓	✓	✓	✓
States/meso	✓		✓	✓		
Organisational/meso	✓			✓		
Individual clinicians/micro	✓					

	Policy	NDIS	Learned clinical colleges	Aged care	Primary care	Hospitals	Laboratories
Role, purpose	Multiple institutional and organisational policy requirements	Regulation for funding of disability and disability insurance	For example, the Royal Australasian College of Physicians; Australian College of Nursing	Multiple levels of aged care regulation	Multiple aspects of primary care regulation	Multiple regulatory requirements for the governance of hospitals, quality of care, and safety of care	Regulation of and accreditation of testing and laboratories
Federal/central/macro	✓	✓		✓	✓		
States/meso	✓	✓		✓		✓	✓
Organisational/meso	✓			✓	✓	✓	✓
Individual clinicians/micro	✓		✓	✓	✓	✓	✓

AHPRA Australian Health Practitioner Regulation Agency, *IHPA* Independent Hospital Pricing Authority, *ACSQHC* Australian Commission on Safety and Quality in Health Care, *TGA* Therapeutic Goods Australia, *PBAC* Pharmaceutical Benefits Advisory Committee, *NDIS* National Disability Insurance Scheme

or penalties and also because of the public interest test, for which there are imperatives that providers must satisfy; but also because of the ensuing reputational damage if they fail to comply with relevant regulation. For instance, no pharmaceutical company or medical device provider wants to cause morbidity or mortality which could be attributed to their products, and hospitals or general practices with major adverse events or safety lapses occasioning patient harm or deaths must avoid causing such serious incidents as much as they are able to do so.

However, healthcare has not always been successful in complying with requirements, in contrast, say, with aviation. There are thousands of adverse events and violations annually, and inconsistent adherence to known measures to improve the quality and safety of care, such as the variable use of checklists in operating theatres.

4.5 Self-Regulation on the Front-Lines of Care

It follows that top-down forms of regulation such as those presented in Table 4.2 are not the full picture. Healthcare professionals do not merely respond to regulation, but also self-regulate. It may not seem obvious to say so, but so do patients.

Clinicians on the front-lines (e.g., surgeons, general practitioners, psychologists) have considerable degrees of autonomy as to the evidence they consult or treatments they provide, for example, and patients today have more agency and have a greater say in their care compared with past eras. Thus, providers (and, more frequently these days, patients) are able to self-regulate—professionals, by the treatment choices they make, and patients, by the decisions they make in accepting, rejecting, or adhering to clinical recommendations. Research associated with the 60-30-10 paradigm suggests that 40% of care does not follow the available level 1 evidence or current clinical guidelines (Braithwaite et al. 2018c). A proportion of such non-adherence is attributable to clinical choices and patients and relatives exercising their preferences.

There are also pressures within and across health professional teams to act appropriately and conform with professional standards. As well, although they are subject to formal regulation discussed above, clinicians nevertheless tend to act ethically, in the interests of patients, and with forethought most of the time (Bringedal et al. 2018). However, healthcare incentives can act perversely, and mean that volume and patient throughput can be privileged over value and outcomes, and celebrated regulatory lapses such as in the famous UK case of serial murderer Dr Harold Shipman (Jackson and Smith 2004), and when hospital cultures become toxic and usher in a major inquiry (e.g., The Bristol Royal Infirmary Inquiry ('Bristol Royal Infirmary Inquiry' 2002)) are illustrative of the limits of self-regulation, and showcase when clinicians fail patients or systems break down, or both.

4.6 Theoretical Paradigms of Interest

Regulation has also been subject to theoretical interest in healthcare. There are many theories of regulation, some of which are healthcare-specific and others which have been formulated elsewhere, and applied to healthcare. Examples include 'interest theories' (whereby the regulator attempts to maximise social welfare and acts for the benefit of society), 'toll booth theories' (whereby regulation is enacted for the benefit of governments and bureaucrats through which they can extract rent or votes) and 'principal-agent theories' (whereby the government-regulator acts as the principal and the regulatee as the agent in a contractual relationship) (Boehm 2007). Each of these theoretical considerations can play a role in understanding regulatory structures in healthcare. A key recent conceptual development is the regulation of the patient journey championed by Vincent and Amalberti (2016). They argue that regulation must broaden its approach to take account of the patient's journey, rather than be static, and mainly concerned to regulate individuals, care episodes, or organisations at a point in time:

> Regulatory agencies face some major new challenges. Until now most regulation has focused on individual healthcare professionals or specific organisations and institutions. Regulation in its various forms now needs to extend to encompass new organisational forms and the complex series of transitions and interfaces along the patient journey … Traditional approaches … may have to be adapted considerably. To move from accreditation of structures and institutions to accrediting patient journeys across primary, secondary and home care is a huge challenge. (Vincent and Amalberti 2016, p. 155)

Such an approach may well signal future developments in healthcare regulation. Everyone (patients, clients, care recipients) is on a journey—from birth to death, and from being in the community to passing through the health system at multiple junctures, for example. To be focused on the person as they transition, interacting with healthcare in its myriad, changeable forms, and cope with technological and organisational change across time, shifts the very idea of regulation from a relatively passive, cross-sectional endeavour to a dynamic pursuit. Whether regulation can become more dynamic, and more longitudinally responsive in the way Vincent and Amalberti (2016) advocate is a practical question of consequence for the future.

4.7 Discussion and Conclusion

Regulation has permeated healthcare, particularly over the last three decades, in different ways, with wide-ranging applications, and at multiple systems levels. Despite the variety of regulatory authorities and types of regulation, ranging from accreditation standards, policy, enacted legislation, and taxation to name only a few, there have nevertheless been breaches, violations, accidental errors, and substandard

care provided across healthcare systems and markets. These have caused considerable concern among regulators and regulatees and led to regulatory agencies and bodies to become more active. This has also created, across different healthcare systems, complex and often fragmented regulatory ecosystems.

Paradoxically, things go right far more than they go wrong and the Safety-II approach is increasingly recognised as an important regulatory paradigm. When they do go wrong, considerable risks and harm to patients ensue, with consequential effects including on providers themselves (the 'second victim') (Wu 2000). This has traditionally been a major stimulus for regulation. Self-regulation is also important in healthcare and relies on professional ethics, training, and ongoing education. Patient choice is another self-regulatory mechanism.

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References

R. Amalberti, *La conduite de systèmes à risques: le travail à l'hôpital* (Presses universitaires de France, Paris, 1996)

R. Amalberti, Y. Auroy, D. Berwick, P. Barach, Five system barriers to achieving ultrasafe health care. Ann. Intern. Med. **142**(9), 756–764 (2005). https://doi.org/10.7326/0003-4819-142-9-200505030-00012

Australian Government Department of Health (2021) Our Portfolio. Available at: https://www.health.gov.au/about-us/who-we-are/our-portfolio

R. Axelrod, M. Cohen, *Harnessing Complexity: Organizational Implications of a Scientific Frontier* (Free Press, New York, 2000)

F. Boehm, *Regulatory Capture Revisited–Lessons From Economics of Corruption* (Univeridad Externado de Colombia, Colombia, 2007)

J. Braithwaite, K. Churruca, L.A. Ellis, J. Long, R. Clay-Williams, N. Damen et al., *Complexity Science in Healthcare* (Australian Institute of Health Innovation, Macquarie University, Sydney, 2017)

J. Braithwaite, K. Churruca, J.C. Long, L.A. Ellis, J. Herkes, When complexity science meets implementation science: a theoretical and empirical analysis of systems change. BMC Med. **16**(1), 1–14 (2018a). https://doi.org/10.1186/s12916-018-1057-z

J. Braithwaite, R. Mannion, Y. Matsuyama, P.G. Shekelle, S. Whittaker, S. Al-Adawi, *Healthcare Systems: Future Predictions for Global Care* (CRC Press, Boca Raton, 2018b)

J. Braithwaite, P.D. Hibbert, A. Jaffe, L. White, C.T. Cowell, M. Harris, S. Muething, Quality of health care for children in Australia, 2012–2013. JAMA **319**(11), 1113–1124 (2018c). https://doi.org/10.1001/jama.2018.0162

J. Braithwaite, P. Glasziou, J. Westbrook, The three numbers you need to know about healthcare: the 60-30-10 challenge. BMC Med. **18**, 1–8 (2020). https://doi.org/10.1186/s12916-020-01563-4

B. Bringedal, K. Isaksson Ro, M. Magelssen, R. Forde, O.G. Aasland, Between professional values, social regulations and patient preferences: medical doctors' perceptions of ethical dilemmas. J. Med. Ethics **44**(4), 239–243 (2018). https://doi.org/10.1136/medethics-2017-104408

Bristol Royal Infirmary Inquiry (London, England: The Stationery Office, Crown Copyright 2002)
G.L. Daumit, E.M. Stone, A. Kennedy-Hendricks, S. Choksy, J.A. Marsteller, E.E. McGinty, Care coordination and population health management strategies and challenges in a behavioral health home model. Med. Care **57**(1), 79–84 (2019). https://doi.org/10.1097/MLR.0000000000001023
L.E. Dodge, S. Haider, M.R. Hacker, Knowledge of state-level abortion laws and policies among front-line staff at facilities providing abortion services. Women's Health Issues **22**(5), e415–e420 (2012). https://doi.org/10.1016/j.whi.2012.07.002
E. Fenton, Equity and preventive regulations. J. Med. Ethics **45**(5), 329–330 (2019). https://doi.org/10.1136/medethics-2019-105352
E. Hollnagel, *Safety-II in Practice: Developing the Resilience Potentials* (Taylor & Francis, Abingdon, 2017)
E. Hollnagel, J. Braithwaite, R. Wears, *Resilient Health Care* (Ashgate Publishing Company Burlington, Farnham, 2013)
T. Jackson, R. Smith, Harold shipman. BMJ **328**(7433), 231 (2004). https://doi.org/10.1136/bmj.328.7433.231
L. Jovic, E. Bianchi, S. Decouflet, V. Loizeau, P. Amiot, M. Teixeira, Nurses in France: between autonomy and subordination in front line care. Global Qualit. Nursing Res. **2** (2015). https://doi.org/10.1177/2333393615584550
M. Knaapen, M.C. Ploem, M. Kruijt, M.A. Oudijk, R. van der Graaf, P.M. Bet et al., Low-risk trials for children and pregnant women threatened by unnecessary strict regulations. Does the coming EU clinical trial regulation offer a solution? Euro. J. Pediat. **179**(8), 1205–1211 (2020). https://doi.org/10.1007/s00431-020-03715-3
D.B. Kramer, S. Xu, A.S. Kesselheim, How does medical device regulation perform in the United States and the European union? Syst. Rev. Plos Med. **9**(7), e1001276 (2012). https://doi.org/10.1371/journal.pmed.1001276
E. Oikonomou, J. Carthey, C. Macrae, C. Vincent, Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare. BMJ Open **9**(7), e028663 (2019). https://doi.org/10.1136/bmjopen-2018-028663
A. Rose, K.B. Filion, M.J. Eisenberg, C. Franck, Electronic cigarettes: a comparison of national regulatory approaches. Can. J. Publ. Health **106**(6), e450–e453 (2015). https://doi.org/10.17269/cjph.106.5043
K. Vasiljeva, B.H. van Duren, H. Pandit, Changing device regulations in the European Union: impact on research, innovation and clinical practice. Indian J. Orthop. **54**(2), 123–129 (2020). https://doi.org/10.1007/s43465-019-00013-5
C. Vincent, R. Amalberti, *Safer Healthcare: Strategies for the Real World*, (Cham (CH), Springer Nature, 2016)
M.M. Waldrop, *Complexity: The Emerging Science at the Edge of Order and Chaos* (Viking, London, 1992)
R.L. Wears, E. Hollnagel, J. Braithwaite. in *Resilient Health Care, Volume 2: The Resilience of Everyday Clinical Work* (London, CRC Press, 2015)
T.M. Wilkinson, Obesity, equity and choice. J. Med. Ethics **45**(5), 323–328 (2019). https://doi.org/10.1136/medethics-2018-104848
A.W. Wu, Medical error: the second victim: The doctor who makes the mistake needs help too. BMJ **320**(7237), 726–727 (2000). https://doi.org/10.1136/bmj.320.7237.726
B.K. Yang, M.E. Johantgen, A.M. Trinkoff, S.R. Idzik, J. Wince, C. Tomlinson, State nurse practitioner practice regulations and U.S. health care delivery outcomes: a systematic review. Med. Care Res. Rev. **78**(3), 183–196 (2021). https://doi.org/10.1177/1077558719901216